

137



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|                 |             |                      |                     |                  |
|-----------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/019,588      | 12/20/2001  | Frederic Andre       | SANSYL002           | 1696             |

|      |      |            |
|------|------|------------|
| 5487 | 7590 | 08/10/2005 |
|------|------|------------|

ROSS J. OEHLER  
AVENTIS PHARMACEUTICALS INC.  
ROUTE 202-206  
MAIL CODE: D303A  
BRIDGEWATER, NJ 08807

|                    |  |
|--------------------|--|
| EXAMINER           |  |
| FUBARA, BLESSING M |  |

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1618     |              |

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/019,588

**Applicant(s)**

ANDRE ET AL

**Examiner**

Blessing M. Fubara

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) 6,16-23 and 25-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of power of attorney filed 04/25/05 and 05/16/05; amendment and remarks filed 05/24/05. Claims 1, 3, 4, 6-9 and 11-34 are pending. Claims 24 and 34 are withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 103***

1. Claims 1, 3, 4, 7-9 and 11-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Heinicke et al. (US 5,834,024) in view of Staniforth et al. (US 5,725,883).

Applicants argue that it is only with hindsight that one would have picked and chosen from the list of surfactants in the instant specification because Staniforth discloses compositions that contain any cationic or zwitterionic surfactant and that Staniforth talks only about effective amount and does not disclose any desire for generating a delayed release coated core.

#### ***Response to Arguments***

2. Applicants' arguments filed 05/24/05 have been fully considered but they are not persuasive.
3. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Art Unit: 1618

4. In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Staniforth is relied upon for a suggested disclosure that diltiazem can be formulated with cationic surfactant such as benzalkonium chloride. The primary reference discloses diltiazem formulation that contains surfactants without indicating that the surfactant is cationic or anionic or zwitterionic. It is thus proper to rely on a reference that suggests using effective amount of cationic surfactant with diltiazem.

5. The rejection of claims 1, 3, 4, 6-9, 11-23 and 25-33 under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 6,403,597) is withdrawn because Eudragit or ammonio methacrylate coating material is not disclosed from the prior document, US 6,037,346 upon which the 6,403,597 patent derives priority; applicants' argument is persuasive.

The prior art made of record, cited in the last Office action and not relied upon is considered pertinent to applicants' disclosure. Mughal et al. (US 4,524,060) discloses sustained release pharmaceutical composition that comprises active agent, wetting agent or surfactant, disintegrants and EUDRAGIT R1- and RS enteric coating (abstract; column 2, lines 10-18; column 3, lines 6-38). Staniforth et al (US 5,858,412) discloses sustained release formulation comprising active agents, microcrystalline cellulose, cationic surfactant, EUDRAGIT RL and EUDRAGIT RS sustained release coatings (column 10, lines 17-33 and 53-58; column 1, lines

Art Unit: 1618

15-34 and 59-63; column 20, lines 17-32; column 21, lines 13-18; column 22, lines 14-22).

Mughal and Staniforth (US 5,858,412) are equal importance as the reference cited above.

6. Claims 6, 16-23 and 25-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In this case, Heinicke et al. (US 5,834,024) in view of Staniforth et al. (US 5,725,883) does not disclose cocamidopropylbetaine zwitterionic surfactant and the limitations of claim 16.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

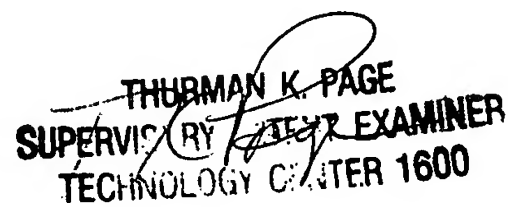
Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara  
Patent Examiner  
Tech. Center 1600



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600